MINUTES OF THE
MEDICAL MARIJUANA FACILITIES WORKGROUP
INDEPENDENT TESTING LABORATORIES
OCTOBER 4, 2013

The Medical Marijuana Facilities Workgroup for Independent Testing Laboratories was called to order by Marla McDade Williams at 9:30 a.m. on Friday, October 4, 2013, in the Legislative Building, Room 1214, Carson City, Nevada. The meeting was videoconferenced to the Grant Sawyer Building, 555 E. Washington, Las Vegas, NV. Offsite attendees accessed the meeting through a conference call number or the Internet.

STAFF MEMBERS PRESENT:

Marla McDade Williams, Deputy Administrator
Chad Westom, Bureau Chief
Kelly Bown, Consultant
Joseph Theile, Management Analyst

OTHERS PRESENT:

Gary Lambert	Cheryl Bricker	Eric Edgerton	Eric Spratley
Pat Coward	Mike Hillerby	Harry Irwin	David Udy
Sandra Tiffany	Henry Soloway	Randy Dockery	John Henry Wright
Serina Choi	Andrew Vires	Jack McGinnis	Shar McGinnis
Robert Allen	Mike Shannon	David Brown	Chuck Callaway
Bruce Gale	Kimberly Rushton	John Sande	Bernalyn Gutierrez
Ralph Wenger	John O'Reilly	Ken Lowery	Lana Hammond
Scott Lopez	David McDonough	Todd Youren	Michael Laguna
John Hiatt	Jacqueline Holloway	Jessica Aragura	Gary Millika
Vicki Higgins	Mike Higgins	William Ballard	Forrest Darby
Karen Becker	Jon Spinogatti	William Horne	Matt Young
Jerome Snyder	Antonio Del Hierro	Penny Perez	Chris Hussey
Kurtis Johnson	James Dean Leavitt	Drew Gennaso	D. Lynn
Delos Benedict	Julie Monteiro	Jay Matos	Paul Larsen
M. McDonald	Marc TerBeek	Steve Cottrell	Randy Haskin
Adam Mintz	Michael Gambino	Michael Betts	Terri Solerno
Amanda Connor	Kate Swander		

Marla McDade Williams:
The Medical Marijuana Workgroup for Independent Testing Laboratories is open. The purpose of this meeting is to go through the proposed concepts for medical marijuana establishments (MMEs) that are independent testing laboratories. I will review the document titled, "Outline of Discussion Points, Medical Marijuana Establishments, Laboratories." Accompanying this document is the document titled, "NRS – NAC Provision Chart." In addition, we have made available the definitions. We will take comments on definitions in written format.

Today, attendees have the opportunity to see the proposed language for the regulations pursuant to Senate Bill (SB) 374 of the 2013 Legislative Session. The Division's goal is to get consensus on the concepts and proposed language of the regulations.

The "NRS – NAC Provision Chart" illustrates how the process began. As a starting point, we first reviewed the Arizona medical marijuana regulations; however, there are some differences between the Arizona and Nevada laws. In addition, the Division has reached out to other jurisdictions that have approved the use of medical marijuana. The proposals contained in this document were adopted by the state of Washington.

Line 30 specifies the prohibitions on financial interest in an independent testing laboratory. In addition, it requires a laboratory to have a scientific director and specifies the role of the director.

Line 31 specifies the qualifications of a scientific director.

Line 32 references the quality assurance standards a laboratory must use; allows an independent third party to assess the analytic testing methodologies used by the laboratory; and specifies the requirements of a laboratory.

Line 33 authorizes the Division to audit and inspect the practices of the laboratory.

Line 34 specifies the monograph that laboratories are required to follow.

Line 35 specifies the quality assurance tests required for marijuana and marijuana products.

Line 36 specifies requirements if a lot of usable marijuana fails a quality assurance test.

Lines 80 through 84 contain repeated language. This repetition is necessary to ensure the Division has captured all of the applicable sections of the bill within the regulations set. The final regulations will not repeat language; the language will be consistent with the concepts from interested parties as the regulations move forward.

We will take public comment.

Mike Hillerby:
The law says there can be one or more laboratories. Will there be a competitive application process? It is apparent that laboratories and cultivation facilities need to be established before dispensaries can be operational.

Ms. McDade Williams:
The law states the need to designate the number of laboratories; however, the Division is analyzing if this is necessary. We know we have to limit the number of dispensaries. We know we must have an adequate ratio of cultivators to dispensaries.

Interested parties should provide the Division their input on whether there should or should not be a designated number of laboratories. At some point, the Division will declare if there will be a designated number of laboratories.

Mr. Hillerby:
We believe Nevada is unique in that it will require licensure of laboratories. Laboratories will be somewhat of a regulatory partner with the State. There is value in careful review of applicants to find those most qualified and to limit the number of laboratories.

Ms. McDade Williams:
Regarding the application process, we agree in theory that we should first certify laboratories and then cultivation facilities.

David Udy:
I understand there is a need for security and confidentiality of testing facilities, but we have the opportunity to point out the public health outcomes related to testing facilities. If we can engage the process so that timely information is received from each facility, we can, for the first time, develop a deeper understanding of cannabis production in the State to include strains and toxicities. This information should be made available to colleges and universities in the State for research opportunities.

Karen Becker:
I represent LV Diagnostics. Can you clarify what "independent" means in terms of laboratories? I noticed in the materials received today it appears that persons who own a cultivation or dispensation facility may not also own a laboratory. However, in reading the statute, one could be an owner of a laboratory and a dispensary, but the product sold must be tested by an independent laboratory.

Ms. McDade Williams:
We will obtain clarification and make that information available on our website.

Henry Soloway:
I have been the director of several laboratories in Las Vegas. There is a long history in the U.S. about good laboratory practices. Those practices have been addressed by the federal government in the Clinical Laboratory Improvement Act (CLIA). The CLIA has been the model for laboratory practices in the U.S. and many locations overseas. In general, the regulations we have should take into account the recommendations in the CLIA. Practices that are not defined in the CLIA should not be performed. I recommend that the regulations be sent to the federal agency that oversees inspection and accreditation so they can be reviewed by someone with experience in laboratory inspection and accreditation review. To be honest, these provisions for laboratories are laughable.

Ms. McDade Williams:
We would be pleased to meet with you to discuss your concerns further. Before this meeting, our staff looked at the CLIA. We want to ensure we are all on the same page before the regulations are finalized.

Vicki Higgins:
Line 23, subsection 2, paragraph (b) states, "a person who holds a valid registry identification card or his or her designated primary caregiver" is allowed to provide dispensaries with medicine. Does that mean a cardholder can give to an MME one time? I recommend that patients be allowed to provide medical marijuana to MMEs to supply the MME needs.

It will be essential that there are quality controls in place to ensure the product is properly tested. In addition, there should be a separate quality control center. Should a business choose to operate a quality control center in addition to other establishment types, I suggest that a separate quality control center be used to test the quality control of the establishment.

Andrew Vires:
Most of the current research is centered on THCs [Tetrahydrocannabinols], CBDs [Cannabidiols], and CBNs [Cannabinoids]. The American Medical Association acknowledges that there are over 60 other chemicals that can potentially provide benefits to patients. Because Nevada has chosen to license laboratories, this provides a unique opportunity for Nevada. Specifically, the legislation identifies the three main chemicals as beneficial to patients, but does not identify these other chemicals. Identifying the other chemicals would strengthen the legislation.

John O'Reilly:
How can attendees obtain copies of the handouts? How will future documents be distributed?

Ms. McDade Williams:
We have distributed all documents through the medical marijuana LISTSERV. The LISTSERV can be accessed on the Division's website. In addition, documents are posted on our website. We will accept emails, letters, and telephone calls through the end of October.

The Division is working to prepare a regulation set and post the document for an upcoming workshop. We will take public comments through the date of the workshop. It is an open comment period for the month of October. Once the formal document is prepared, we will have a final workshop for comments. After the workshop, the final draft of regulations will then be submitted to the Legislative Counsel Bureau (LCB); the LCB will prepare their final version of the regulations within 30 days. Once the LCB has returned the regulations, we will post a 30-day notification of a public hearing for adoption of the regulations. Interested parties should submit public comments so they can be incorporated into the final regulations. We believe we are on track to meet the April 1 deadline for adoption of the regulations.

Mr. O'Reilly:
Will you be re-evaluating what has been handed out today between now and early November?

Ms. McDade Williams:
Correct.

Mr. O'Reilly:
Will the comments today as well as those submitted between now and early November be part of the public record?

Ms. McDade Williams:
Yes. Documentation received by the Division will be posted on the website or distributed through the LISTSERV.

John Hiatt:
As written, the law specifies that it must be determined whether marijuana is grown organically. This is not a laboratory issue; this issue needs to be solved by different means such as certification of growers. In addition, while people believe that laboratories can do testing and work miracles, laboratory testing costs money. In determining what the laboratory should test, it is important to understand the costs involved so that the cost of marijuana is not prohibitively expensive. It is also important that laboratories may not get testing right all the time. There needs to be an ongoing mechanism to determine the manner in which laboratories should operate and ongoing revision of testing requirements. Laboratories need to know what they are required to test for and how the test results should be reported.

Ms. McDade Williams:
Regarding your comment about ongoing revision, this may be something that we struggle with because we are required to work from the regulations. We need to have language that gives us the authority to adjust testing requirements. If interested parties are aware of any models from other states that have language we can use, that would be helpful.

James Dean Leavitt:
One of the concerns and significant flaws in the legislation is that there has been no limit placed on the number of laboratories. The cost to set up a laboratory can run into the millions of dollars. If you look across the Nation, many laboratories have been unsuccessful. Because we have so few cardholders in the State, I have concerns that it will take many years for laboratories to recoup their investments. It is my understanding that laboratories will be certified first, but I fear they will be idle while they wait for the cultivation facilities to be licensed. Then, there will be a delay in licensing dispensaries. Laboratories could have a one- or two-year investment before a return is seen. I recommend that the number of laboratories be limited to two. When you decide to let the market determine how this works, it concerns me greatly.

Ms. Higgins:
If we are able to get the production and cultivation facilities licensed within at least one grow cycle before the law is in place and the dispensaries open, quality control centers will be quite busy.

Unidentified Caller:
I received information that there is grant money that will be released. Has that happened yet?

Ms. McDade Williams:
I am not aware of that issue. You may follow up with Joseph Theile on that issue.

Steve Cottrell:
I am with a laboratory in Arizona. Line 83 addresses most of the laboratory testing; however, it does not address pesticide testing. Pesticides are a toxic chemical that will be used in the growing process. Pesticide testing must be addressed because it can negatively affect patients.

Ms. McDade Williams:
We will obtain Arizona's regulations and address that issue.

Randy Haskin:
Have you considered the regulations Massachusetts put in place? Massachusetts is the first state to require that laboratories be ISO [International Organization for Standardization] certified. Washington is headed in that direction as well.

Ms. McDade Williams:
We will consider the Massachusetts regulations.

Adam Mintz:
I agree that pesticide testing should be performed.

I suggest that you look at the Connecticut regulations on the palliative use of marijuana. These regulations include testing for pesticides and heavy metals as well as testing for micotoxins, terpenes, and any cannabinoids that are over one percent.

Michael Gambino:
Regarding the suggestion to limit the number of laboratories to two, another issue is the timing of them becoming operational. Laboratories could be made operational but may have to wait for licensing of the other establishment types. Laboratories should not have to be idle while waiting for other establishments to be operational.

Michael Betts:
Regarding comments to limit the number of laboratories to two, establishments will need to have the opportunity to have alternate testing performed. Limiting the number of laboratories to two would hurt everyone in general.

Regarding the timeline for licensing, there is a minimum of four months for a cultivation facility to have product. This will allow for establishments to be rolled out and to ensure that quality testing is performed.

I am not sure what the process is for obtaining samples. Will laboratory staff personally obtain samples from cultivators? Otherwise, will cultivators be able to transport samples directly to laboratories?

Terri Solerno:
Regarding the packaging after laboratory testing, will this be a secondary process? Will the product be returned to the cultivator for packaging prior to going to dispensaries?

Ms. McDade Williams:
We intend that there be a chain of custody as product is moved from the cultivator to the other establishments. We will ensure that the chain-of-custody provisions are clear in the regulations.

Amanda Connor:
I believe it will not be sufficient to limit the number of laboratories to two in the State. Other states that require laboratory testing have shown that if there are various laboratories, there can be quality control of each laboratory. In addition, laboratories need to be in close proximity to cultivators to allow timely testing. Limiting the number of laboratories will not provide for enough quality control.

Ms. Higgins:
Two quality control centers in the Las Vegas area will be adequate. Northern Nevada should have at least one.

Mr. Cottrell:
How many tests need to be performed of a certain batch? This needs to be clarified.

Mr. Mintz:
Regarding the residual solvent testing, it is important that the State determine the appropriate parts per million (ppm) that will be required for this testing. The state of Washington currently uses 500 ppm for residual solvent testing.

Mr. Betts:
Will electronic verification systems be required to be uniform? Will establishments have to have the same systems?

Ms. McDade Williams:
There is no requirement for establishments to have the same type of system; however, as a regulatory agency, we must ensure that electronic verification systems operate properly. We will consider the comments received today for inclusion in our final draft document.

This workgroup is adjourned at 10:30 a.m.

RESPECTFULLY SUBMITTED:

Sara Weaver,
Administrative Assistant

APPROVED BY:

Marla McDade Williams, Deputy Administrator

DATE: _____